UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,117	09/22/2003	Kieko Morita	030096A	5419

38834 7590 02/23/2005

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP
1250 CONNECTICUT AVENUE, NW
SUITE 700
WASHINGTON, DC 20036

EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,117	MORITA, KIEKO	
	Examiner	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2004 and 29 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 11/29/04 wherein claims 1-27 are canceled and claim 30 is added.

Note: Claims 28-30 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT

2. The Applicant's arguments filed 11/29/04 to the rejection of claims 23 and 26-29 made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed persuasive for reasons of record. Therefore, all outstanding rejections are hereby withdrawn.

NEW GROUNDS OF REJECTIONS

103 Rejections

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peskind et al (Neurology, 2001, Vol. 56, pp. 1094-1098).

Peskind et al disclose that increased cerebrospinal fluid cortisol levels were detected in Alzheimer's subjects. In particular, it is disclosed that the authors measured

cortisol levels in cerebrospinal fluid and determined that APOE genotypes for subj3ects with Alzheimer's disease was higher (see entire document, especially, abstract; page 1095, 'Methods'; pages 1096-1098, 'Discussion'). However, Peskind et al fail to specifically state that a drug should be administered to lower the cortisol level in subjects.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Peskind et al and generate methods of detecting and treating Alzheimer's disease wherein cortisol levels in the cerebrospinal fluid is analyzed because the cited prior art is directed to a study that indicated that an increase in cerebrospinal fluid cortisol in Alzheimer's disease subjects (in relation to controls) is a function of APOE genotype. Furthermore, it would be obvious to one of ordinary skill in the art to administer a medication that reduces the level of cortisol level to normal because in the discussion of Peskind et al it is set forth that subjects with higher cortisol lever at greater risk of Alzheimer's than persons with lower cortisol. Thus, a skilled practitioner would be motivated to administer medications that would lower the cortisol level in cerebrospinal fluid as a means of decreasing a subject's chance of Alzheimer's.

5. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swaab et al (Journal of Neuroendocrinology, 1994, Vol. 6, pp. 681-687).

Swaab et al disclose that increased cortisol levels was found in subjects with Alzheimer's disease. The cerebrospinal fluid of the subjects was analyzed in relation to

that of controls (see entire document, especially, abstract; pages 681-683, 'Results; pages 683-684, 'Discussion'; page 685 'Materials and Methods'). However, Swaab et al fail to specifically state that a drug should be administered to lower the cortisol level in subjects.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Swaab et al and generate methods of detecting and treating Alzheimer's disease wherein cortisol levels in the cerebrospinal fluid is analyzed because the cited prior art is directed to a study wherein it was found that increased cortisol levels in the cerebrospinal fluid was found in subjects having Alzheimer's disease. Furthermore, it would be obvious to one of ordinary skill in the art to administer a medication that reduces the level of cortisol level to normal because in the discussion of Swaab et al it is set forth that subjects with higher cortisol lever at greater risk of Alzheimer's than persons with lower cortisol. Thus, a skilled practitioner would be motivated to administer medications that would lower the cortisol level in cerebrospinal fluid as a means of decreasing a subject's chance of Alzheimer's.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1616

February 18, 2005